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Attachment 11

K010099
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510(k) Summary

Jan. 9, 2001

1. Submission Applicant & Correspondent:

Name:	Zynergy CardioVascular, Inc.
Address:	298 Fernwood Ave. Edison, NJ 08837
Phone No.:	(732) 225-3800
Contact Person:	Ms. Jing Zhang

2. Name of Device:

Trade/Proprietary/Model Name:	Zynergy Z3K Balloon Guided Pacing & Monitoring Catheter
Common or Usual Name:	Flow-Directed Pacing and Monitoring Catheter
Classification Names:	Flow-Directed Catheter; Temporary Electrode Pacemaker

3. Devices to Which New Device is Substantially Equivalent:
Zynergy Z3K Balloon Guided Pacing & Monitoring Catheter is substantially equivalent to Zynergy BalloonPace Balloon Guided Pacing and Monitoring Catheter, and Zynergy Z4 Transvenous Bipolar Pacing Catheter.

4. Device Description:
The Z3K catheter was designed and tested in accordance with the applicable sections of ISO 10555-1:1995, Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements.

The Z3K catheter is comprised of a radiopaque polyurethane main body tube with two platinum electrodes and a latex balloon attached on distal end and a molded polyurethane junction on the proximal end which provides attachment for lead wire assemblies and balloon lumen access.

The product is packaged individually with a volume-limited syringe as a single use disposable device and shipped ETO sterilized.

5. Intended Use of the Device:
The Zynergy Z3K Balloon Guided Pacing & Monitoring Catheter is intended for use in temporary transvenous ventricular cardiac pacing and monitoring as in the management of impaired impulse formation or conduction.

6. Summary of Technological Characteristics of the Device Compared to the Predicate

Devices:
The Zynergy Z3K Balloon Guided Pacing & Monitoring Catheter has the same intended/indications for use, design, construction, technological characteristics, and product range as the predicate BalloonPace device. The only differences between the Z3K catheter and the predicate BalloonPace device are in the material used for the catheter's main body tube and the number of junction boots used at the proximal end. These changes do not raise any new issues of safety or effectiveness as demonstrated by the biocompatibility test results and comparable results from the design verification testing.

The Zynergy Z3K Balloon Guided Pacing & Monitoring Catheter has the same intended/indications for use and material (except the colorant – no colorant is added to the Z3K main body tube) as the predicate Z4 catheter.

7. Tests and Conclusions:
Extensive functional and performance testing, and biocompatibility testing were conducted to assess the safety and effectiveness of the Zynergy Z3K Balloon Guided Pacing & Monitoring Catheter. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Jing Zhang
Manager, Regulatory Afairs/Quality Assurance
Zynergy CardioVascular, Inc.
298 Fernwood Ave.
Edison, NJ 08837

Re: K010099
Trade Name: Zynergy Z3K Balloon Guided Pacing and Monitoring Catheter
Regulatory Class: II (two)
Product Code: LDF
Dated: January 9, 2001
Received: January 11, 2000

Dear Ms. Zhang:

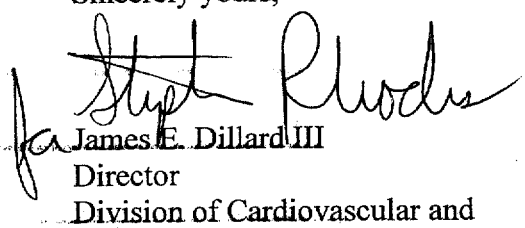
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010099

Device Name: Zynergy Z3K Balloon Guided Pacing and Monitoring Catheter

Indications For Use:

The Zynergy Z3K Balloon Guided Pacing and Monitoring Catheter is indicated for use in transvenous ventricular cardiac pacing and monitoring as in the management of impaired impulse formation or conduction.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010099

(Optional Format 3-10-98)